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Assessing the effectiveness of constitutional approach and sector approach in the management of chronic rhinosinusitis along with the assessment of quality of life among adults: A quasi experimental study

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Abstract

Background: Chronic rhinosinusitis is defined as a symptomatic inflammation of the paranasal sinuses and nasal cavity persisting for more than 12 weeks and is characterised by mucopurulent discharge, nasal obstruction, facial pain/pressure/fullness, and decreased sense of smell. In India, 1 in 8 individuals, or 5 to 15% of the urban population, suffer from chronic rhinosinusitis. This study aims to compare the constitutional and sector approaches for treating chronic rhinosinusitis symptoms by assessing SNOT22 scores and quality of life.

Aim: To assess and compare the effectiveness of constitutional approach and sector approach in the management of Chronic Rhinosinusitis along with the assessment of quality of life among adults.

Methodology: This is a prospective, non-randomised, interventional study. Seventy subjects were selected by purposive sampling who fulfilled the diagnostic, inclusion, and exclusion criteria from the Government Homoeopathic Medical College and Hospital, Bengaluru. Subjects were divided into two groups, Group A and Group B, of thirty-five subjects each. Data was collected by detailed case taking and recorded in the standardised case proforma. Selection of the remedy for group A was done through the constitutional approach, and for group B, the sector approach. The Sino Nasal Outcome Test 2022 was used for outcome assessment during follow-up, and a paired t test was used for statistical evaluation.

Results: The study found that out of 35 subjects in group A, 22.9% recovered, 68.6% improved, and 8.6% did not show improvement, while in group B, only 2.9% recovered, 54.3% improved, and 42.9% did not show improvement, indicating a statistically significant difference in treatment outcomes.

Interpretation and Conclusion: The study reveals that the Homoeopathic medicines selected through the constitutional approach are more effective than the sector approach in the treatment of Chronic Rhinosinusitis.

Keywords: Chronic Rhinosinusitis; paranasal sinus; constitutional approach; Sector approach; Snot 22; quality of life

Introduction

Chronic rhinosinusitis is defined as a symptomatic inflammation of the paranasal sinuses and nasal cavity persisting for more than 12 weeks [1]. CRS with or without nasal polyps is characterized by two or more symptoms, one of which should be either nasal blockage, obstruction, congestion, or nasal discharge (anterior/posterior nasal drip) with or without facial pain/pressure; and/or with or without reduction or loss of smell [2].

The maxillary sinus is mostly involved. Chronic sinusitis is usually the result of incompletely resolved acute sinusitis [3].

There is an overlap in the symptoms of sinusitis and rhinitis, and sinusitis rarely manifests alone [4]. Second, there is an important interrelationship between the middle turbinate and the ethmoid sinus; the cyclic variations in nasal turbinate swelling occurring during the normal nasal cycle can cause mucosal thickening in the ethmoidal infundibulum. One may interpret this thickening as ethmoid sinusitis. The ethmoid infundibulum and the nose represent contiguous structures sharing vascular, neuronal, and interconnecting anatomic pathways. For these reasons, some expert panels have adopted the term rhinosinusitis, as defined in some expert reports [5].

Affecting 10 to 15% of the global population, chronic rhinosinusitis (CRS) is one of the most prevalent chronic and disabling diseases. Antibiotics, nasal decongestants, topical nasal steroids and/or oral steroids, saline irrigation, and surgery are some of the current management techniques, the outcomes are highly variable. In the National Ambulatory Medical Care Survey, sinusitis ranks as the sixth most often treated medical condition that requires antibiotics. A Cochrane study found that antibiotics only slightly improve basic (uncomplicated) sinus infections. However, the advantage may be outweighed by the drugs' unfavourable side effects on the patient and the general community. Only 5 out of 100 individuals receiving antibiotics healed faster, according to a recent Cochrane Review, and these patients also experienced much greater negative side effects [1].

It has been shown that it raises the risk of mood and sleep disorders as well as depression and anxiety. Due to this disease, there is significant patient morbidity in terms of negatively affected quality of life and substantial impairment of daily functioning, resulting in decreased overall productivity [1].

In India, 1 in 8 individuals, or 5 to 15% of the urban population, suffer from chronic rhinosinusitis (CRS) [6].

In a study conducted in Telangana, Harika Surapaneni and Shalini Singh found that over 75% of patients in the 16-45 age group had sinusitis. Chronic sinusitis affected 25 patients (41.7%) in the 16-30 age group and 22 patients (36.7%) in the 31-45 age group (p. 14). 60% of the patients were males and 40% were girls [7].

A study on individualized homoeopathic medicines in Chronic Rhinosinusitis: randomized, double blind, placebo controlled trial used SNOT20 questionnaire. 62 subjects were taken, 31 in each group. Although improvements in both primary and secondary outcome measures were higher in the IH group than placebo, with small to medium effect sizes, the group differences were statistically non-significant (all $p > 0.05$, unpaired t-tests) [1].

The observational study on individualized homoeopathic treatment in chronic rhinosinusitis with follow-up of 8 years. They included 134 subjects, who had been suffering from sinusitis for 10.7±9.8 years The improvements in health-related QoL were of smaller effect size but statistically significant. The latter was confirmed by Mee-Chua-tests for the mental component score (P=0.0859, P=0.034, and $p<0.0001$ at 3, 12 and 24 months) but not for the physical component score (P=0.6869, P=0.6859, and P=0.1259) after administering Individualized homoeopathic medicine [8].

A multicentric study conducted at four CCRH centres as a randomised, double-blind, placebo-controlled trial with three months of treatment and three months of observations revealed the effectiveness of homoeopathic remedies in the treatment of chronic rhinosinusitis with improvements in Total symptom score (TSS) and Sino nasal Outcome Test (SNOT22). In that study, 394 patients who were followed up demonstrated complete recovery in 138 individuals, and there had been no relapse during the year of follow-up [9].

An open-label, single arm study conducted on 628 patients suffering from chronic sinusitis. Seventeen homeopathic medicines were shortlisted based on repertorization of the disease symptoms. The scale used as the outcome measure was a chronic sinusitis assessment score that was developed by the CCRH. Positive results were detected ($p<0.0001$) and the need of a controlled trial was mentioned [10].

The institution-based study, Prospective Analysis to Evaluate the Role of Concha Bullosa in Chronic Rhinosinusitis, included 110 patients over the age of 10 who were clinically confirmed as having chronic rhinosinusitis in accordance with the criteria of the rhinosinusitis task force. Headache constituted 85.4% of all clinical symptoms, followed by nasal obstruction at 80%. Nasal discharge or nasal purulence, which was present in 74.5% of cases, was the second most frequent complaint. The demographics of study population revealed that the middle-aged group with a male predominance had a higher prevalence of both CRS subtypes. Surprisingly, the CRSwNP group showed a stronger prevalence [11].

In Evaluation of the ostiomeatal complex's anatomical variations using a CT scan. 90% of the patients reported having a headache, which was followed by nasal discharge in 86.6% of cases and nasal obstruction in 85.33% [12].

The American Academy of Otolaryngology-Head & Neck Surgery's task force on rhinosinusitis developed the working definition (AAO-HNS). Adult rhinosinusitis diagnostic criteria were established by the American Academy of Otolaryngology Head & Neck Surgery (AAO-HNS) interdisciplinary Rhinosinusitis Task Force in 1996 [13, 14].

In a cross sectional study, evaluating the change in recent diagnostic criteria in case of chronic rhinosinusitis have come to conclusion that two out of 4 symtoms given in revised AAO HNS criteria are sufficient to diagnose chronic rhinosinusitis [15].

To ascertain the psychometric validity of the 22-item Sinonasal Outcome Test (SNOT-22), a modification of the SNOT-20, a disease-specific health-related quality-of-life tool for use in chronic rhinosinusitis. The SNOT-22 has proven to be reliable and simple to operate. It can be utilised to show how chronic rhinosinusitis affects a patient's quality of life through ordinary clinical practise [16].

A Retrospective Study Evaluating the Usefulness of 50 Millesimal Potencies in the Treatment of Chronic Diseases. The totality was generated once the symptoms were categorised. Constitutional prescriptions were founded on the sum of the analysis and evaluation of the mental generals, physical generals, defining characteristics, and miasm given. It was noted that 25 out of 50 instances received constitutional prescription treatment, while the remaining received sector prescription treatment. Results indicate that of those receiving constitutional treatment, 56% showed a considerable improvement, 36% showed a modest improvement, and 8% showed no improvement [17].

Hahnemann speaks of a person's innate nature in aphorism number five. In regard to the Latin root "constiture," Hahnemann used the German word "Beschaffenheit", which is typically rendered as "constitution".

Aphorism 5 states that Useful to the physician in assisting him to cure are the particulars of the most probable exciting cause of the acute disease, as also the most significant points in the whole history of the chronic disease, to enable him to discover its fundamental cause, which is generally due to a chronic miasm. In these investigations, the ascertainable physical constitution of the patient (especially when the disease is chronic), his moral and intellectual character, his Occupation, mode of living and habits, his social and domestic relations, his age, sexual function, &c., are to be taken into consideration [18].

Sector totality

As sickness develops, there is first a widespread disturbance in the human economy brought on by a dysfunctional dynamic. As there hasn't been enough localisation for the clinician to establish a diagnosis, this might be referred to as a "sickness" rather than a "disease". The disease process is currently in the prelocalization stage. The involvement of various sectors or locales in the illness process increases as it spreads. When the localization has taken place and allows the doctor to establish a clinical diagnosis, this may be referred to as a "disease". Any system, tissue, or organ in the body may be impacted by this localization of the overall disturbance, as well as many organs and systems. As the illness process continues to worsen, once again there is the generalized disturbance in the human economy with the affection of the general sector, i.e. there occurs progressive involvement of vital organs and functions, with their resultant complications and sequelae.

Sector totality is thrown up when the different sectors get affected subsequently. These variable expressions of the sector totality depend on the various sectors/ locations and the characteristic sensations and pathology in Boger's terminology.

Sector totality

1. Location-systems, organs, tissues and region
2. Sensation and pathology
3. Diagnostic and characteristics
4. Ailment from-cause
5. Aggravations and ameliorations in the sectors [19]

Few studies have used individualized constitutional homoeopathic medicine based on mentals, physicals and characteristic particulars in the management of chronic rhinosinusitis with statistical significant outcomes [8, 9].

An open-label, single arm study where Seventeen homeopathic medicines were shortlisted based on repertorization of the disease symptoms. Positive results were detected (p<0.0001) and the need of a controlled trial was mentioned [10].

Hence this study is intended to assess if there are any differences between choosing the similimum based on sector totality or constitutional totality for the treatment of chronic rhinosinusitis symptoms.

Methodology

Study Setting: The subjects for the study will be chosen from the Out Patient Department / In Patient Department of the Government Homoeopathic Medical College and Hospital, Bengaluru.

Study Subjects: Subjects diagnosed with chronic rhino sinusitis based on AAO-HNS revised criteria will be divided into 2 groups, namely Group A and Group B.

Group A: Subjects will be treated with the constitutional Homoeopathic approach.

Group B: Subjects will be treated with sector homoeopathic approach.

Criteria for selecting subjects under Group A and Group B is as follows

Group A	Group B
Totality of symptoms formed on the basis 1. Mentals 2. Physical generals 3. Characterictic particulars	Totality of symptoms formed on the basis 1. Location 2. Sensation 3. Modalities 4. Concomitant

Sample Size: 70 subjects, 35 each in group A and group B.

Study Period/Duration: 18 months.

Study Design: Comparative quasi experimental study.

Sample Design: Purposive sampling

- If subjects adhere to the criteria given under group A then they will be included in the constitutional approach.
- If subjects adhere to the criteria given under group B then they will be included in the sector approach.

Type of Research: Interventional comparative study.

Follow-UP:

- The severity and intensity of the symptoms of the subjects will be assessed using the snot22 scoring system on the first visit to determine the baseline score and at the end of the study.
- Follow up of the cases will be done once in 15 days for the first 3 months and once in a month for the next 3 months.
- In case of any medicinal aggravation, mitigation intervention will be provided if necessary, time and date of the same will be recorded.
- The subject will be explained in detail about the research phenomena in their own language, and after confirming that he/she understood the phenomena and is willing to participate, his/ her consent will be obtained in the written form.

Diagnostic criteria

Diagnosis will be based on

American Academy of Otolaryngology and Head and Neck Surgery revised criteria for chronic rhino sinusitis:

- Twelve weeks or longer of two or more of the following signs and symptoms:
- Mucopurulent drainage (anterior, posterior, or both)
- Nasal obstruction (congestion)
- Facial pain-pressure-fullness
- Decreased sense of smell.

Inclusion criteria

- Subjects aged between 18-60 years
- Diagnosed cases will be made through AAO HNS criteria
- Subjects who are willing to participate and sign the written informed consent form.

Exclusion criteria

- Subjects suffering from Systemic illness or immunocompromised or any vital organ failure or any malignancy.
- Subjects who are receiving treatment from homoeopathic system or other systems of medicine for the same complaint or any other complaint.
- Subjects suffering from the complication of chronic rhinosinusitis.
- Subjects with deviated nasal septum.
- Pregnant women and Lactating mothers.

Method of collection of data

After obtaining approval from institutional ethics committee, those who fulfil the inclusion and exclusion criteria, 70 subjects will be recruited to the study. Data will be collected by detailed case taking through direct personal interview method using case record form according to the instructions given in the sixth edition of organon of medicine. Assessment of the symptom severity and quality of life will be done using SNOT22 questionnaire. The medicine for each group will be selected either on the basis of Constitutional Totality (Group A) or Sector Totatlity (Group B). The potency selection and repetition of the doses will be done according to Homoeopathic principles of posology aphorism 246-258 of organon of medicine sixth edition.

- **Consent:** The subject will be explained in detail about the research phenomena in their own language, and after confirming that he/she understood the phenomena and is voluntarily willing to participate, his/ her consent will be obtained in the written form.
- **Proposed Statistical Analysis:** The data collected for this study will be analyzed statistically in the following ways.
- **Descriptive statistics:** The categorical variables will be presented in the form of frequency distribution tables with percentage. The quantitative variables described by computing descriptive statistic namely mean and standard deviation or median and interquartile range subjected to normality assumption verification. 95% confidence interval for mean and proportion will also be computed.
- **Inferential statistics:** The difference in means of the score pre tested for their significance using unpaired (independent sample) t-test for comparison between the groups and paired t-test for comparison within the groups provided the data follows normal distribution, if not the non-parametric test namely Mann Whitney "U" test and Wilcoxon Signed-Rank Sum test. For assessing the changes in the follow-up data paired t test will be applied.

The differences in outcome measure of recovered, improved and not improved will be tested by means of standard normal variant (Z) test.

The results will be considered statistically significant whenever $p \leq 0.05$.

Outcome assessment

Parameters used: SNOT22 questionnaire

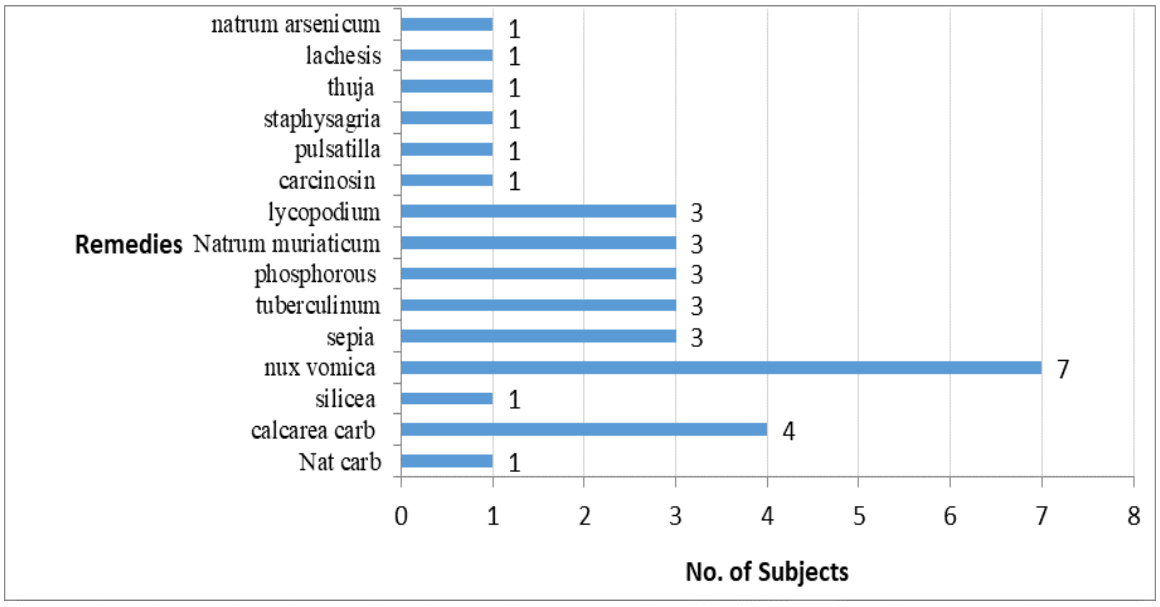
In SNOT 22 score out of 110 scoring

- If percentage of improvement lies between 94% to 100% following treatment then it is considered as recovered.
- If percentage of improvement lies between 49%-94% following treatment, then it is considered to be improved.
- If percentage of improvement lies between 0%-48% following treatment then it is considered to be not improved. Even after 3 months of treatment, if there is no improvement, it will be considered as dropout and treated in general OPD.

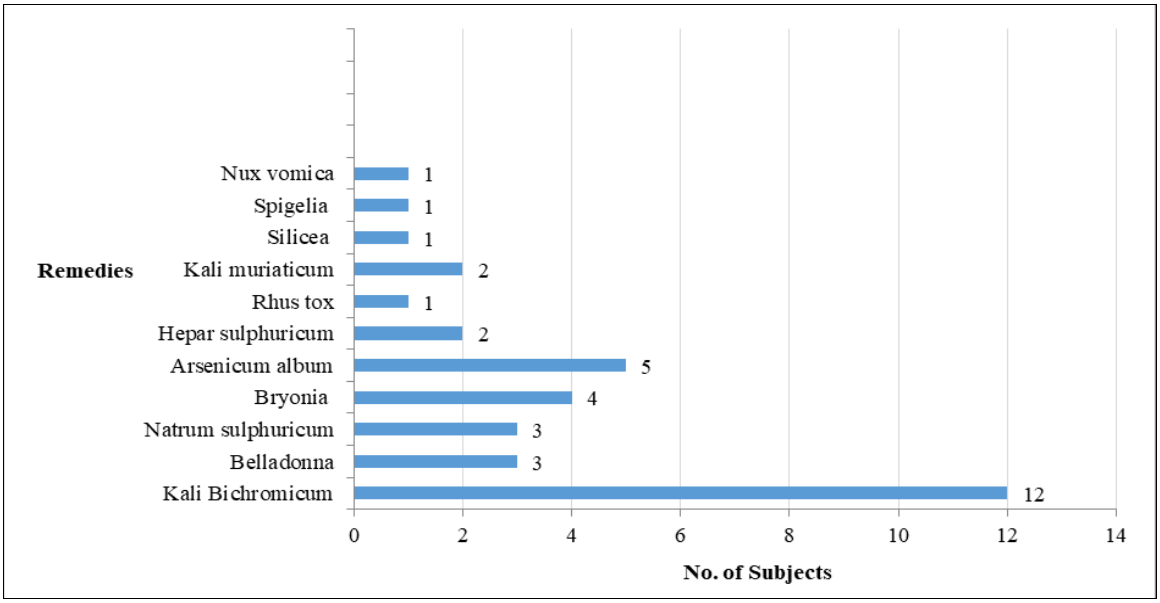
Results

In the present study, 70 subjects who attended the Government Homoeopathic Medical College and Hospital, Bengaluru, OPD, and IPD were included after being screened for the inclusion and exclusion criteria. Based on the presentation of symptoms, the subjects were categorized into two groups.

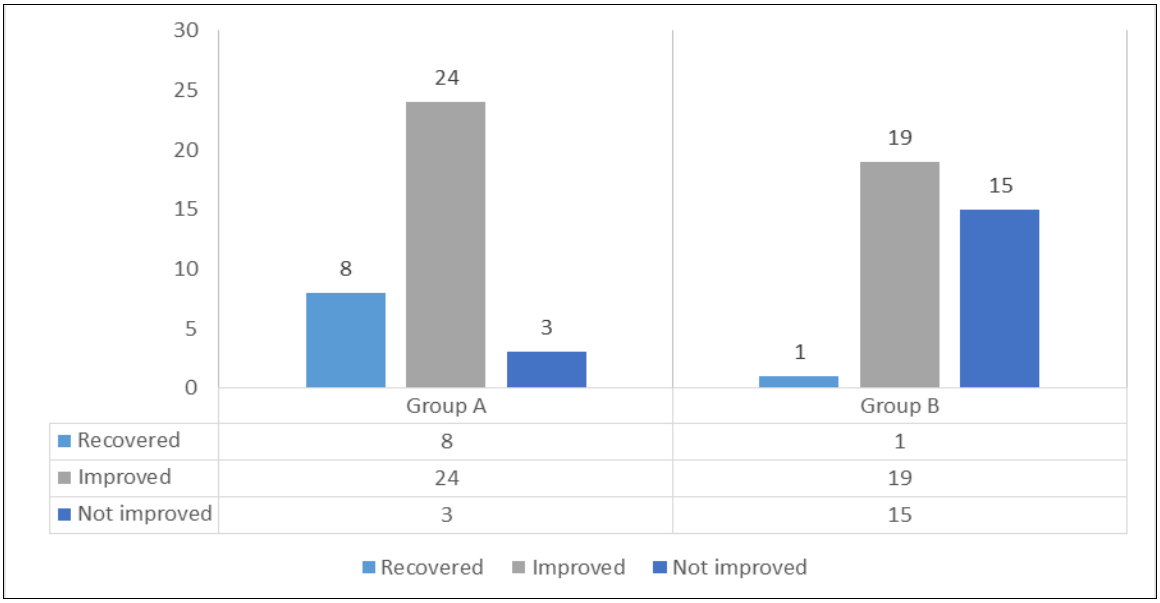
- **Group A:** Treated with constitutional approach.
- **Group B:** Treated with sector approach..



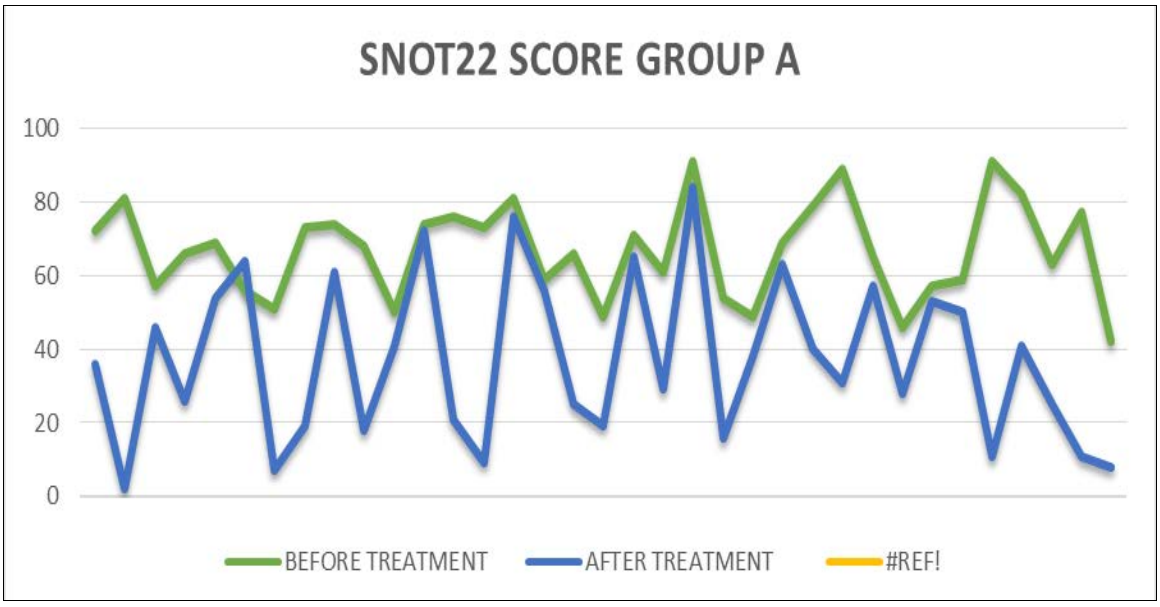
Graph 1: Horizontal bar diagram according to distribution of remedies in Group A



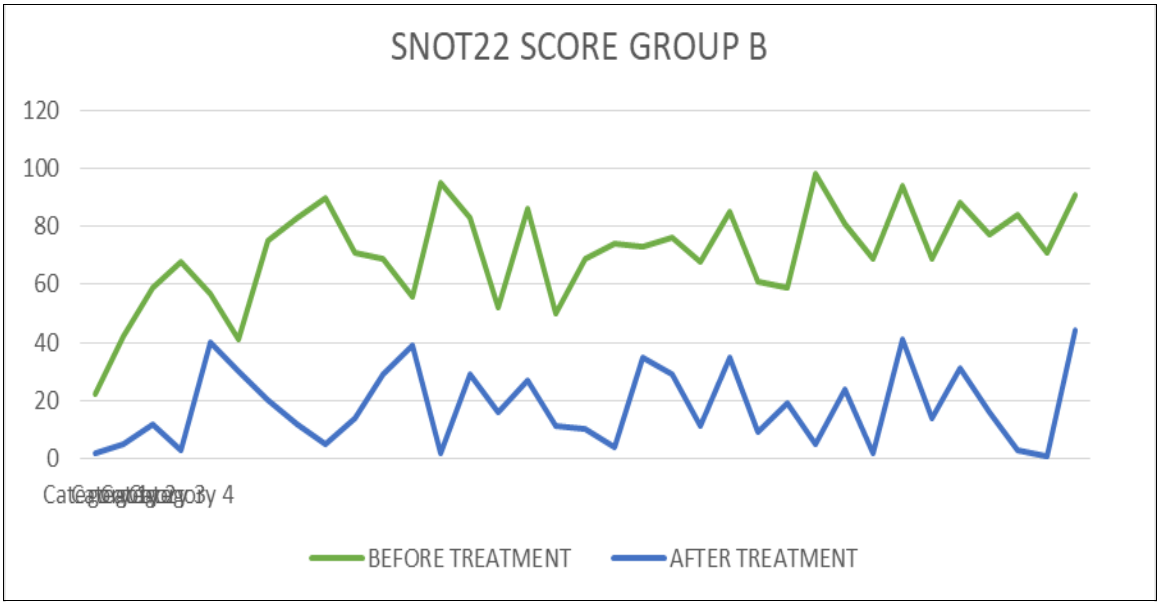
Graph 2: Horizontal bar diagram according to distribution of remedies in Group B



Graph 3: Bar chart showing comparison of outcome of Group A and Group B



Graph 4: Line diagram showing distribution of subjects according to SNOT22 Score before and after treatment in Group A



Graph 5: Line diagram showing distribution of subjects according to SNOT22 Score before and after treatment in Group B

The follow-up of these subjects was carried out every 15 days for 3 months and every month for rest 3 months for a period of 6 months as per the individual requirements. The inferences drawn from the statistical analysis performed on the gathered data have been noted below

In Group A, amongst the 35 subjects treated with individualized remedies, nux vomica was the most frequently indicated remedy (Graph 1). In Group B, amongst the 35 subjects treated with sector approach, kali bichromicum was the most frequently indicated remedy (Graph 2).

Out of 35 subjects in group A, 8 (22.9%) recovered, 24 (68.6%) improved, and 3 (8.6%) did not show any improvement. In Group B out of 35 subjects, 1 (2.9%) recovered, 19 (54.3%) improved, and 15 (42.9%) did not show improvement at the end of the study period (Graph 3).

Distribution of subjects according to SNOT22 Score before and after treatment in Group A and group B is given in Graph 4.

Descriptive and Inferential Statistics

Comparison within the group

After applying Paired t test, it was observed that there is a significant change in group A and group B (P=0.000<0.05) with 74.70% and 44.36 decrease in the score respectively. Further, post hoc analysis was performed and found that the change is highly significant at (P=0.000 < 0.05) and thereby concluding that the treatment with both Individualized medicines in Group A and sector approach in Group B are effective (Table 1 and 2).

Comparison between the groups

When an effect is compared between the groups using the Z test, it is found that there is a significant difference at P=0.0001 < 0.01. So, it is inferred that Group A is better than Group B (Table 3).

To compare the treatment outcomes of both Groups A and B, the Chi square test was applied. After verifying the table, the value obtained was 14.026, and the p-value is 0.001. Therefore, there is a highly significant difference between groups A and B with respect to improvement after the intervention, which shows group A is better when compared to group B (Table 4).

Table 1: Comparison within the constitutional approach

Group	Mean		Std. Deviation	Mean difference	S.D of difference	Change (%)	Paired t-test value	P	
Constitutional approach	SNOT 22 Value Before	71.03	16.925	53.06	19.80	74.70	15.86	0.000	HS
	Snot 22 Value-After	17.97	13.363						

Table 2: Comparison within the sector approach

Group		Mean	Std. Deviation	Mean difference	S.D of difference	Change (%)	Paired t-test value	P	
Sector approach	SNOT 22 Value-Before	66.86	12.984	29.66	23.78	44.36	7.38	0.000	HS
	SNOT 22 Value-After	37.20	22.173						

Table 3: Z-Test for comparison between the group

					IQR			
		Mean difference	S.D of difference	Median	Lower	Upper	Z-Value	P-Value
Pre-Post	Sector Approach	29.66	23.78	32.00	8.00	44.00	4.047	0.0001, HS
	Constitutional Approach	53.06	19.80	55.00	40.00	65.00		

Table 4: Comparison of outcome of Group A and Group B

		Group					
		Group A		Group B		Total	
		Count	Column N%	Count	Column N%	Count	Column N%
Outcome	Recovered	8	22.9%	1	2.9%	9	12.9%
	Improved	24	68.6%	19	54.3%	43	61.4%
	Not Improved	3	8.6%	15	42.9%	18	25.7%
	Total	35	100.0%	35	100.0%	70	100.0%

Chi square = 14,026, P=0.001, HS

Inference

The main inferences based on the various statistical tests applied can be summed up as follows:

- Paired t-test was applied for the analysis of "within the group" data, and it was found that the treatment in both groups were effective.
- The Z test was applied for the analysis of "between the groups" data, and it was found that treatment of Group A is better than treatment of Group B.
- A Chi Square test was performed to analyze the data on treatment outcomes, and it was found that there is a significant difference between groups A and B, and group A is better when compared to group B.
- Therefore, research hypothesis is accepted and null hypothesis is rejected.

Thus, according to statistical results, it is found that the efficacy of constitutional approach is greater when compared to the efficacy of a sector approach.

Discussion

Sinusitis is one of the most common respiratory infections that impairs a patient's quality of life and reduces productivity at work. Since sinus inflammation cannot occur without some degree of nasal inflammation (rhinitis), more recent classifications of sinusitis call it rhinosinusitis. This chronic illness significantly impacts finances due to the high cost of diagnostic procedures, medical and surgical treatments, reduced productivity at work and school, and adverse effects on both mental and physical health.

It is becoming more common and causes high medical expenses. Sinusitis is the sixth most prevalent condition for which an antibiotic is administered, according to data from the National Ambulatory Medical Care Survey. It is a widespread disease that affects about 30% of all people at some point in their lives.

It is defined as an inflammation of the nasal mucosa and paranasal sinuses for at least 12 weeks which may cause nasal blockage or congestion, mucous discharge, facial pain or pressure, and/or impaired smell

Conventional treatment is directed at enhancing mucociliary clearance, improving sinus drainage/outflow, eradicating local infection and inflammation, and improving access for topical medications. Intranasal corticosteroid sprays and nasal saline irrigation are the first-line treatments. Antibiotics may be useful in treating people who have signs of an acute sinus infection that is active and superimposed, while they can momentarily alleviate symptoms. Endoscopic sinus surgery is performed if medical therapy is ineffective. Inadequate treatment for chronic rhinosinusitis can result in many problems, including a decrease in quality of life. In a variety of situations, homoeopathic remedies have been proven to be highly effective in preventing recurrence and enhancing quality of life, particularly in respiratory disorders.

This study was a prospective, comparative clinical study which was conducted to assess the effectiveness of Constitutional approach and sector approach in the treatment of chronic rhinosinusitis. This study was carried out for 6 months from February 2023 to august 2024.

Seventy subjects were selected on the basis of inclusion and exclusion criteria and divided into two groups of thirty-five subjects each, based on the purposive sampling method. Chronic Rhinosinusitis was diagnosed based on the criteria of AAO HNS. Group A was treated with constitutional approach, and Group B was treated with sector approach. The study subjects were selected from the OPD and IPD of the Government Homoeopathic Medical College and Hospital, Bengaluru.

- The information from the subjects was taken in detail and recorded in the standardized case proforma, and assessment was done using SNOT22. The statistical analysis made in this study is based on the data obtained from these seventy subjects.
- The main results that emerged from this study are as follows:

1. In this study, there was a statistically significant reduction in the intensity and frequency of exacerbations of Chronic Rhinosinusitis. This shows that both Constitutional approach and sector approach had a good therapeutic role in the treatment of chronic rhinosinusitis.
2. However, on comparison of the statistical values of both groups, constitutional approach proved to be more effective than sector approach in the treatment of chronic rhinosinusitis.

Finally, based on the statistical analysis made using the above data, the null hypothesis was rejected and the research hypothesis was accepted. Therefore, constitutional approach has a significantly better effect in the treatment of chronic rhinosinusitis than the sector approach. Each group was analyzed by comparing their respective Snot22 in the beginning and at the end of the study, to prove that each group produced significant improvement.

Limitations

- As the study was time-bound, the cases could not be followed beyond the limited time period.
- The sample size could have been larger so that the results obtained could be more generalizable.
- As the sample size is limited to 35 subjects in each group, generalizing the results and drawing conclusion from the study must be done with the caution.
- Purposive sampling method was used, which is subjected to bias.

- The assessment scale used in the present study, SNOT22, may not be foolproof; human errors are possible.
- Certain variables, like selection of the appropriate rubrics, quality of medicine, method of dispensing medicine, and placebo effect could not be well assessed.
- Subjects are taken only from the OPD and IPD of the Government Homoeopathic Medical College and Hospital, Bengaluru.

Recommendations

- Further long-term prospective studies with a large sample size must be conducted to explore the efficacy of Constitutional approach in contrast with that of sector approach in the management of chronic rhinosinusitis.
- It is better to draw samples using simple randomization along with blinding to minimize the errors that may happen in the case of purposive sampling.
- It is better to do a control study to know the efficacy of medicines i.e. in comparison with conventional treatment.
- It is better to use CT scan as a follow up Criterial for the evidence based result.

Conclusion

This study was conducted for the period of 6 months that both medicine selected based on constitutional approach and sector approach are seen to have adequate therapeutic responses in the treatment of chronic rhinosinusitis. On the other hand, in comparison, it is seen that the constitution approach is more effective than the sector approach in the treatment of Chronic Rhinosinusitis by assessing SNOT22 score which includes symptoms and quality of life. The null hypothesis is rejected and the research hypothesis is accepted

Conflict of Interest: Not available

Financial Support: Not available

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